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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/714,365 | 11/14/2003 | Stephen A. Yencho | 148 | 1868 |
| 33109 | 7590 | 05/16/2005 | EXAMINER | |
| CARDICA, INC. 900 SAGINAW DRIVE REDWOOD CITY, CA 94063 | | | GHERBI, SUZETTE JAIME J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,365

Applicant(s)

YENCHO ET AL.

Examiner

Suzette J Gherbi

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/29/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's RCE dtd 4/29/05 has been received in application serial number 10/714,365.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 8-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gifford, III et al. 5,695,504. Gifford, III et al. discloses the structure and methods of the invention as claimed noting figures 24a-24d; and 25a-25d comprising: an inner element (284) connectable to a graft vessel wherein the inner element *includes a unitary body having a closed perimeter and an opening there through with the perimeter*; wherein at least a portion of the unitary body is deformable from a first configuration to a second configuration and deformable back to the first configuration (see col. 31, lines 55-57) and wherein the second configuration allows at least a portion of the unitary body to enter the opening in the target vessel and wherein the device is capable of performing an anastomosis between a graft vessel and a target vessel; and an outer element configured to engage the inner element to hold a portion of the graft vessel and a

portion of the target vessel (see fig. 24b element "285"); wherein the outer element directly engages the inner element; wherein the inner element includes a curved first surface and wherein the curved first surface and curved second surface each have a substantially constant radius of curvature along their lengths; wherein at least one of the inner elements and outer elements is superelastic (see col. 9, lines 65-67; col 10, lines 1-2; including an interlocking member configured to engage the outer element (see col. 3, lines 58-60).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford III et al. in view of Kleshinski 5,755,778. Gifford III et al. has been disclosed above however, Gifford does not specify the material of Nitinol. Kleshinski teaches that anastomosis devices with expandable properties can be made from the material Nitinol (see col. 3, line 56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the invention of Gifford III et al. from Nitinol as

taught by Kleshinski because Gifford discloses that super elastic alloys are envisioned for the invention see col. 9-10, line 66-1).

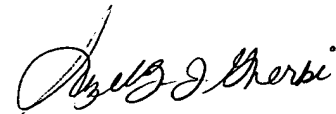
Response to Arguments

6. Applicant's arguments filed 4/29/05 have been fully considered but they are not persuasive. Applicant quotes case law and definition of anticipation and contends that Gifford does not describe each and every element of claims 1 and 11. Specifically applicant contends that Gifford does not disclose deformability of the inner flange 284 from the second configuration back to the first configuration.

7. The examiner believes that the office action under 102 for anticipation is proper. Gifford teaches the structure as claimed and because the device discloses that the flange 284 undergoes expanded and unexpanded configurations *it is capable* of going from the second configuration back to the first configuration. It is also inherent that before the flange 284 is condensed into the unexpanded state that it is expanded. In other words, the first state of the flange is uncompressed (even if it's not illustrated) i.e. during the manufacturing process. The second state can be compression/un-expansion to fit within the opening 267 in the target vessel wall. The final state can be the expansion back to the first configuration. Since these are article claims the applicants arguments are not persuasive because Gifford does have all of the structure as claimed including suggested materials of nickel titanium (see col. 28, lines 20-21) which are capable of undergoing and performing the functions (*methods*).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.
9. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.
10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Suzette J-J Gherbi
11 May 2005